



CleanFlex® Tyvek® / HDPE sterilizable bags

Microbiologically impermeable - yet breathable: Tyvek® offers extremely high resistance at a low weight. Tyvek® packaging provides moisture vapor permeability for sterilization while maintaining microbiological impermeability and broad resistance to abrasion and aging. Bischof+Klein sterilizable bags enable sterilization without the risk of contamination.

CleanFlex® sterilizable bags – standard range

Code	External size	Internal size	Qty. / full pal.	Qty. / box
STTH20	200 x 350 mm	180 x 300 mm	10,010 pcs.	500 pcs.
STTH32	320 x 450 mm	300 x 400 mm	4,410 pcs.	200 pcs.
STTH40	400 x 550 mm	380 x 500 mm	4,010 pcs.	200 pcs.
STTH50	500 x 650 mm	480 x 600 mm	4,010 pcs.	200 pcs.
STTH100	1,000 x 1,230 mm	980 x 1200 mm	810 pcs.	100 pcs.

Standard packaging

- Bags in 2 protective bags
- Bundles in small cardboard boxes
- Pieces per pallet as listed above
- 10 customer samples per pallet

- STTH20: 100 bags / bundle
- STTH32: 100 bags / bundle
- STTH40: 100 bags / bundle
- STTH50: 100 bags / bundle
- STTH100: 20 bags / bundle

Standard packaging

- HDPE V7 film – 80 µm
- Uncoated Tyvek® 1073B

Standard printing

- CleanFlex® and full description
- Bischof+Klein code number
- Bischof+Klein lot number for full traceability
- Indicator dot for steam sterilization (pink / brown)

Full traceability

- IR spectrum as proof of material origin
- Certificate of analysis for every production run
- Optional lot number embossing on all bags
- Full labeling of bundles and pallets
- Documentation of entire process

Certification and quality assurance

- IR spectrum of HDPE film
- Dimensions and thickness
- Seal strength
- Particle class 200 as per IEST-STD-CC-1246E
- ISO 9001: 2015
- ISO 15378 : 2017

Laboratory options

- Additional integrity testing
- Additional age testing
- Additional material testing
- Additional analytical testing

Regulatory compliance*

- Regulation (EU) 10/2011 (most recent edition) – food-approved
 - Compliant to FDA 21 CFR
 - 94 / 62 / EC and CONEG – heavy metal declaration
 - EMA 410 / 01 regulation – BSE / TSE statement
- * After ordering, official certificates / statements will be issued based on the individual material.

Long-term stability analysis

- No change in physical properties (5 years)
- No change in physical properties when autoclaved (5 years)
- No change in indicator functionality (5 years)

Consistency of supply policy

- Announcement of raw material changes 2 years prior to implementation
- Strict change control procedures for process changes
- Call-off orders and warehousing as options for contracted business

Clean room production

- Particle and biological monitoring in place
- Qualification as per DIN ISO 14644-1 class 5, at rest:
 - Extrusion of HDPE film
 - Cleaning of Tyvek®
 - Printing on Tyvek®
 - Conversion
 - Bundling and packing

Tailor-made

- Customized printing
- Full Tyvek® packaging material also possible
- Other indicator labels and prints for other sterilization options

Sterilization options

- Designed for steam sterilization up to 125°C / 15 – 20 min.
- Suitable for ethylene oxide gassing
- Suitable for plasma sterilization
- Suitable for gamma irradiation
- Certificate of irradiation can be provided

The client is responsible for the suitability of the products for their intended applications. The property values shown are based on a limited number of tests and therefore should not be construed as product specifications.